

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)	
)	
Wayne E. CORNISH et al.)	Group Art Unit: 3736
)	
Application No.: 09/746,144)	Examiner: Jonathan M. Foreman
)	
Filed: December 21, 2000)	
)	
For: SUPERELASTIC GUIDEWIRE)	Confirmation No.: 2421
WITH LOCALLY ALTERED)	
PROPERTIES)	

Attention: Mail Stop Appeal Brief-Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed on September 29, 2008, and further to Board Rule 41.37, Appellants present this brief and enclose herewith the fee of \$510.00 required under 37 C.F.R. § 1.17(c).

The time period for filing an appeal brief was reset to be one-month from the mailing date of the Notice of Panel Decision from Pre-Appeal Brief Review mailed on November 18, 2008. Accordingly, this Appeal Brief is timely filed with the petition for three month extension of time and fee filed herewith.

This Appeal responds to the May 30, 2008, Final Office Action ("Final Office Action") that maintained the rejection of claims 7 and 20-26.

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Real Party In Interest

Abbott Cardiovascular Systems Inc. is the real party in interest, as evidenced by the assignment recorded in the U.S. Patent Office at Reel No. 011701, Frame No. 0275 on April 17, 2001.

Related Appeals and Interferences

There are currently no other appeals or interferences, of which Appellants, Appellants' legal representative, or Assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 7 and 20-26 are pending. Claims 1-6 and 8-19 have been cancelled.

Claims 7 and 20-26 stand rejected and are appealed. No claims have been allowed.

In accordance with 37 C.F.R. § 41.37(c)(1)(viii), the attached Appendix contains a clean copy of the pending claims.

Status of Amendments

No claim amendments have been made in response to or subsequent to the
Final Office Action dated May 30, 2008.

Summary of Claimed Subject Matter

The present invention relates generally to an elongated guiding member for medical devices, such as a guidewire, comprising a superelastic member having at least one section with one or more altered properties. See specification at 3, lines 9-11. The superelastic member comprises a nickel-titanium alloy. *Id.* at 4, lines 2-3. In one embodiment, the altered property comprises a section of the superelastic member that exhibits reduced superelasticity with respect to the rest of the superelastic member. *Id.* at 3, lines 12-14.

In another embodiment, which is recited in **independent claim 7**, the invention relates to an elongated device for medical procedures comprising a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties. *Id.* at 4, lines 4-16; and claim 7. The second set of properties have been altered from the first set of properties by atmospherically isolating a section of the superelastic member and alloying the second section by exposing the section to a diffusable element. *Id.* at lines 6-9. The easily diffusable element is selected from the group consisting of oxygen, hydrogen, and nitrogen. *Id.* at lines 12-14; claims 7, 20, and 21. The second section treated with the easily diffusable element has a reduced superelasticity as compared with the first section of the superelastic member. *Id.* at lines 14-16; claim 22. Thus, in one embodiment, the altered properties comprise reduced superelasticity. *Id.* at 10, line 22 to 11, line 2.

In one embodiment, the second section of the superelastic member having the altered properties comprises a distal end of the superelastic member. *Id.* at 6, lines 15-22; Figs. 3-4, and claim 23.

In one embodiment, the distal end is at least about 3 cm in length. *Id.* at 11, lines 12-13, and claims 24 and 26.

Grounds of Rejection

A. Claims 7 and 20-26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Anderson (U.S. Patent No. 6,325,766) in view of Stevens (U.S. Patent No. 5,722,981). Final Office Action at 2.

B. Claims 7 and 22-26 under 35 U.S.C. § 103(a) as allegedly unpatentable over Yamauchi (JP04187159A) in view of Abel (U.S. Patent No. 6,428,317). Final Office Action at 3.

Argument

Each claim of the present application is separately patentable, and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. § 282. The arguments set forth below are arranged under subheadings, and in accordance with 37 C.F.R. § 41.37(c)(1)(vii), these subheadings indicate the claims whose patentability is argued separately.

I. Rejection of Claims 7 and 20-26 under 35 U.S.C. § 103(a) over Anderson in view of Stevens

Claims 7 and 20-26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Anderson (U.S. Patent No. 6,325,766) in view of Stevens (U.S. Patent No. 5,722,981). Final Office Action at 2.

The Examiner asserts that Anderson discloses “an elongated medical device having a superelastic member (12) having a first set of properties and an adjacent second section (14) having a second set of properties.” *Id.* The Examiner acknowledges, however, that Anderson “fails to disclose the alloy including an easily diffusible element consisting of oxygen or hydrogen.” *Id.*

To remedy this deficiency, the Examiner relies on Stevens, alleging that “Stevens teaches a nickel-titanium alloy having a reduced superelasticity which includes oxygen or hydrogen.” *Id.* The Examiner concludes that “it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one alloy for the other to achieve the predictable results of allowing the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape.” *Id.* Appellants respectfully disagree and traverse this rejection.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q. 2d 1385 (2007), the Supreme Court confirmed that the “framework for applying the statutory language of §103” was still based on its landmark decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). As detailed below, it is evident that the Examiner has not established a *prima facie* case of obviousness in light of the *KSR* decision.

A. Neither Anderson nor Stevens discloses or suggests treating a superelastic member with hydrogen, oxygen, or nitrogen

Anderson and Stevens, individually or in combination, fail to disclose or suggest the claimed invention set forth in claim 7 and all claims dependent therefrom for at least the following reasons.

1. Anderson fails to teach a superelastic member having more than one section and each section having a different set of properties

Contrary to the Examiner’s assertion, Anderson does not disclose “a superelastic member (12) having a first set of properties and an adjacent second section (14) having a second set of properties.” Final Office Action at 2. Rather, the only superelastic member in Anderson is a distal portion (14) of a guidewire (10). Anderson at col. 2, lines 39-43

Anderson teaches a guidewire (10) comprising a proximal portion (12) “formed from substantially nickel-free high-nitrogen austenitic stainless steel alloy” (*Id.* at col. 2, lines 13-17) and a distal portion (14) that can be formed from “pseudo- or super-elastic alloys and shape memory alloys, such as nickel-titanium alloys (Nitinol in particular).” (*Id.* at col. 2, lines 39-43). Anderson discloses that other materials suitable for either the

proximal portion (12) and the distal portion (14) include various forms of stainless steels, or “cobalt based MP35N and L605, and Elgiloy.” *Id.* at col. 2, lines 44-62. Nowhere does Anderson disclose superelastic alloys other than in the distal portion (14). Nothing in Anderson suggests that the distal portion (14) has more than one section or the properties of the superelastic distal portion vary.

2. Anderson fails to teach treating a superelastic member with oxygen, hydrogen, or nitrogen

Further, as the Examiner acknowledges, “Anderson fails to disclose the alloy including an easily diffusible element consisting of oxygen or hydrogen.” Final Office Action at 2. Indeed, Anderson does not disclose treating a superelastic member with hydrogen, oxygen, or nitrogen. The words “hydrogen” and “oxygen” do not even appear in Anderson. The recitations of “nitrogen” are only in the context of “substantially nickel-free high-nitrogen austenitic stainless steel alloy.” Anderson at col. 2 lines 15-16, 50-51, 61-62; col. 3, lines 11-12, 37-40, 41-42, 61-62; and col. 4, lines 25-26.

3. Stevens fails to teach treating a superelastic member with oxygen, hydrogen, or nitrogen

Stevens does not cure Anderson’s deficiencies. It does not disclose treating a superelastic member with any one of hydrogen, oxygen, or nitrogen. Rather, this reference describes using commercially available alloys, teaching that its preferred material is available from Shape Memory Applications, Inc. of Sunnyvale, Calif. See Stevens, col. 3, lines 42-49. To the extent that the alloy purchased from Shape Memory Applications, Inc. contains oxygen and hydrogen, there is no disclosure how these elements are introduced. In any event, one skilled in the art would not find motivation to

treat a section of the superelastic member to alter the properties of that particular section.

4. Stevens fails to teach a superelastic member having more than one section

Further, contrary to the Examiner's assertion that "Stevens teaches a nickel-titanium alloy having a reduced superelasticity which includes oxygen or hydrogen (Final Office Action at 2)," Stevens does not disclose "reduced superelasticity" due to addition of oxygen or hydrogen in the alloy. In fact, the only superelastic members that Stevens disclose are a "suture engaging loop 96" (*Id.* at col. 3, lines 36-57) and a "suture engaging articulating loop 119" (*Id.* at col. 5, lines 48-55). None of the loops 96 and 119 comprises more than one section with differing properties, much less "reduced superelasticity" due to addition of oxygen or hydrogen.

In summary, Anderson and Stevens fails to disclose or suggest the claimed invention for at least two reasons. First, neither teach nor suggest a superelastic member having more than one section. Second, neither teach nor suggest treating the superelastic member so that one section of that member has a different set of properties than the rest of that member. Thus, even if, *arguendo*, one of ordinary skill in the art would have been motivated to combine Anderson with Stevens in the manner suggested by the Examiner, the resulting combination would still fail to teach or suggest each and every element of at least claim 7.

B. The Examiner's arguments regarding the product-by-process claim are not appropriate.

The Examiner argues that "the claimed invention is a product by process type of claim. As such, the claimed invention is not limited to the manipulations of the recited

steps, only the structure implied by the steps. MPEP 2113.” Final Office Action at 3-4. Even if this characterization is appropriate, the structure implied by the instant claims are clearly distinct from Anderson and Stevens.

It is well-known that “[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially ... where the manufacturing process steps would be expected to impart distinctive structure characteristics to the final product.” MPEP 2113. The process of “treating the second section with an easily diffusable element” clearly impart distinctive characteristics to the resulting superelastic member. For example, the second section has the same composition as the first section except that the second section has more hydrogen, oxygen, or nitrogen. Further, to the extent that the addition of hydrogen, oxygen, or nitrogen reduces the superelasticity of the second section, the reduction is in comparison with the superelasticity of the first section.

In contrast, Anderson uses either superelastic NiTi, or stainless steel, or “cobalt based MP35N and L605, and Elgiloy.” Anderson, column 2, lines 13-18, and 38-62. And Stevens discloses a preferred material containing 55.7% Ni, 43.9% Ti, 0.20% Cr, 0.033% C, 0.069% O, 0.0019% H, and 0.0961 other elements. Stevens, column 3, lines 42-46. Nothing in these references remotely suggest a superelastic member having two set of compositions that differ only in their content in hydrogen, oxygen, or nitrogen. Nor do they suggest a superelastic member having one section with a higher superelasticity and another section with a lower superelasticity.

Therefore, Anderson and Stevens, individually or in combination, do not teach a superelastic member having two sections as claimed, and certainly not with the different

properties. Even in combination, these references also do not provide a motivation or suggestion to treat a section of a superelastic member of the claimed invention to alter its properties, as evidenced by the complete lack of teaching in these references on a medical device with a diffusible element. Appellants respectfully request the withdrawal of the rejection based on the above references.

II. Rejection of claims 7 and 22-26 in view of Yamauchi in view of Abel

The Examiner also rejects claims 7 and 22-26 under 35 U.S.C. § 103(a) as unpatentable over Yamauchi (JP04187159A) in view of Abel (U.S. Patent No. 6,428,317). Office Action at 3. The Examiner alleges that Yamauchi discloses the claim limitations, including “treating a second section [of the superelastic member] with an easily diffusible element,” but admits that this reference fails to teach “the easily diffusible element being selected from the group consisting of oxygen, hydrogen and nitrogen.” *Id.* Abel, the Examiner maintains, “teaches that heat treatments and/or the addition of trace elements such as oxygen (O) and nitrogen (N) to nickel-titanium alloys can have very significant effects on desired superelastic properties and performance of the material.” *Id.* at 3. Appellants disagree for at least the following reasons.

A. Yamauchi does not disclose or suggest treating the guidewire with an easily diffusible element

Contrary to the Examiner’s assertion, Yamauchi only teaches heat-treating the base and apex part of a catheter guidewire. See Yamauchi, Abstract. In particular, the Abstract discloses that “in the [aging treatment] treated and hardened C-containing TiNi-type shape memorizing alloy wire, by heat treatment of a part constituting the base part at a temp. lower than 400 °C for 1-30 min and a part constituting the apex part at 400-

500 °C for 1-120 min, twist transmitting properties of the base part and the flexibility of the apex part are provided.” *Id.*

Indeed, nowhere in Yamauchi does it disclose treating the guidewire with an easily diffusable element. The Examiner apparently refers to page 5, lines 1-3 in Yamauchi for the disclosure of “an easily diffusable element.” Final Office Action at 3. Appellants disagree. The followings are pages 4 and 5 from Yamauchi. The paragraph having the last two lines at page 4 and lines 1-3 at page 5 apparently teaches a catheter guidewire having at least the same elasticity in its apex part as a conventional TiNi alloy wire at body temperature (~ 37 °C), and ample rigidity in its base part. Indeed, Yamauchi does not mention oxygen, hydrogen, nitrogen, or “easily diffusable element” anywhere.

B. Abel does not disclose or suggest treating the guidewire with an easily diffusable element

Abel does not teach or suggest diffusing hydrogen, oxygen, or nitrogen into a superelastic alloy after the alloy has been formed. Rather, Abel merely indicates alloys comprising trace amounts of oxygen and/or nitrogen would have different superelastic properties from those without such elements. See Abel at col. 4, lines 7-14. However, this reference does not indicate how oxygen or nitrogen are introduced into the alloy.

Thus, neither Yamauchi nor Anderson disclose treating a superelastic member of a medical device with hydrogen, oxygen, or nitrogen, much less for the purpose of affecting properties of different sections of that superelastic member.

Therefore, even knowing that adding trace elements to the alloy alters the properties of the alloy (if the Examiner’s assertions regarding Abel are believed), and

knowing that heat treatment alters the properties of a guidewire (if the Examiner's assertions regarding Yamauchi are believed), one of ordinary skill in the art would not arrive at the claimed medical device.

Furthermore, Abel is vague on what "significant effects" on what "desired superelastic properties and performance of the materials." See Abel at col. 4, lines 7-14. Hence there is no indication, either in Yamauchi or in Abel, as to why NiTi treated with oxygen, nitrogen, and/or hydrogen would be beneficially used in Yamauchi's device.

For at least the foregoing reasons, Appellants submit that the Examiner has not established a prima facie case of obviousness in rejecting the claimed invention.

Appellants respectfully request the rejections withdrawn.

III. Conclusion

For the reasons given above, pending claims 7 and 20-26 are allowable over the cited references. Appellants respectfully request withdrawal of each of the Examiner's rejection is respectfully requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

/Louis Troilo/

Dated: March 16, 2009

By: _____
Louis M. Troilo
Reg. No. 45,284

Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)

1-6. (Canceled)

7. (Previously Presented) An elongated device for medical procedures comprising a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusable element, wherein said easily diffusable element is selected from the group consisting of oxygen, hydrogen, and nitrogen, and the superelastic member comprises a nickel-titanium alloy.

8-19. (Canceled)

20. (Previously Presented) The elongated device of claim 7, wherein the easily diffusable element is hydrogen.

21. (Previously Presented) The elongated device of claim 7, wherein the easily diffusable element is oxygen.

22. (Previously Presented) The elongated device of claim 7, wherein the altered properties comprise reduced superelasticity.

23. (Previously Presented) The elongated device of claim 7, wherein the second section of the superelastic member having the altered properties comprises a distal end of the superelastic member.

24. (Previously Presented) The elongated device of claim 23, wherein the distal end is at least about 3 cm in length.

25. (Previously Presented) The elongated device of claim 23, wherein the altered properties comprise reduced superelasticity.

26. (Previously Presented) The elongated device of claim 25, wherein the distal end is at least about 3 cm in length.

Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)

No evidence is being relied upon by Appellants in this appeal.

Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)

No related proceedings.